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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/595,916	05/19/2006	Judith Bramel Deely	PB60596USw	8981

23347 7590 10/22/2007

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EXAMINER	
KIM, JENNIFER M	
ART UNIT	**PAPER NUMBER**
1617	

NOTIFICATION DATE	DELIVERY MODE
10/22/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/595,916	DEELY ET AL.	
	Examiner	Art Unit	
	Jennifer Kim	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 August 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6,9 and 10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6,9,10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The response filed on August 8, 2007 have been received and entered into the application.

Action Summary

The rejection of claims 5-10 under 35 U.S.C. 103(a) as being unpatentable over Jerussi et al. (WO 00/51546) in view of Morgan et al. (US 6,274,579 B1) is being maintained for the reasons stated in the previous Office Action. However, the rejection is modified in this Office Action to exclude cancelled claims.

The rejection of claims 5-10 under 35 U.S.C. 103(a) as being unpatentable over Morgan et al. (US 2003/0064988A1) is being maintained for the reasons stated in the previous Office Action. However, the rejection is modified in this Office Action to exclude cancelled claims.

The rejection of claims 5-10 under 35 U.S.C. 103(a) as being unpatentable over Morgan et al. (US 2006/0189612A1) is being maintained for the reasons stated in the previous Office Action. However, the rejection is modified in this Office Action to exclude cancelled claims.

The rejection of claims 5-10 under 35 U.S.C. 103(a) as being unpatentable over Ascher et al. (US 2003/0032643A1) is being maintained for the reasons stated in the previous Office Action. However, the rejection is modified in this Office Action to exclude cancelled claims.

Response to Arguments

Applicants' arguments filed August 8, 2007 have been fully considered but they are not persuasive. Applicants argue that Jerussi et al. document is silent with respect to the treatment of Applicants' claimed "mixed anxiety-depressive disorder" and that Morgan et al. is also silent with respect to the treatment of anxiety. This is not found persuasive because Jerussi et al. teach that bupropion metabolites including (+)-(2S,3S)-2-(3-chlorophenyl)-3,5,5-trimethyl-2-morpholinol are useful for the treatment of anxiety disorders and depression. (page 7, lines 7-10). Morgan et al. teach that the activity of bupropion resides with its (+) enantiomer metabolite, (+)-(2S,3S)-2-(3-chlorophenyl)-3,5,5-trimethyl-2-morpholinol. Accordingly, there is a reasonable expectation of successfully treating mixed anxiety-depressive disorder by employment of the compound known to effectively treat both disorders as taught by Jerussi et al. Applicants argue that Morgan et al. (US 2003/0064988A1) **(I)**, and Morgan et al. (US 2006/018612A1) **(II)**, define "method of treating depression" by specifying particular types of depression thereby treatment of depression-related anxiety symptoms is

contemplated. Therefore, both Morgan et al's patients to be treated principally diagnosed with depression but no disclosure of treating a patient principally suffering from or diagnosed with an anxiety disorder as suggested by the Examiner. This is not found persuasive because both Morgan et al. teach that the compound, (+)-(2S,3S)-2-(3-chlorophenyl)-3,5,5-trimethyl-2-morpholinol, is useful for the treatment of depression wherein the "treatment" involving amelioration of **symptoms**. ([0019]). Therefore, such "treatment" of depression extends amelioration of the symptoms therein. The depressed patients of Morgan et al. to be treated with the compound obviously encompasses treatment of those symptoms accompanying the disease such as depression-related anxiety symptoms because such symptoms were contemplated by the treatment of depressed patients disclosed by Morgan et al. Therefore, there is a reasonable expectation of successfully treating mixed anxiety-depressive disorder with the compound, (+)-(2S,3S)-2-(3-chlorophenyl)-3,5,5-trimethyl-2-morpholinol taught by Morgan et al. effective in treating symptoms of depression-related anxiety symptoms. Applicants further argue that depression-related anxiety symptoms are not the same diseases/condition as mixed anxiety-depressive disorder as set forth in claim 6 of the present application. This is not persuasive because Applicants' attention is drawn to Kara et al. (Psychiatry Research 94(2000)), wherein it teaches that mixed anxiety-depressive disorder patients suffer from both anxiety and depressive symptoms. (abstract). Therefore, the claimed subject matter of mixed anxiety-depressive disorder involving symptoms of depression and anxiety deemed to fail to distinguish over with

depression-related anxiety symptoms taught by prior art. Accordingly, the claims are therefore properly rejected under 35 U.S.C. 103.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 6, 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jerussi et al. (WO 00/51546) of record in view of Morgan et al. (US 6,274,579 B1) of record.

Jerussi et al. teach that bupropion metabolites are useful for the treatment of anxiety disorder, (abstract, page 2, scheme 2, page 7, lines 7-10). Jerussi et al. teach that bupropion metabolites are often referred to as "hydroxybupropion" that has two chiral carbon atoms and exist as two pairs of enantiomer as shown in scheme 2. (page 2, line 9-23, claims). The scheme shows Applicants active agent (+)-(2S,3S)-2-(3-chlorophenyl)-3,5,5-trimethyl-2-morpholinol set forth in claims 6, 9 and 10. Jerussi et al. teaches that the bupropion metabolites can be administered to a patient in an optically pure (S,S)-hydroxybupropion. (claims). Jerussi et al. do not illustrate the administration of the specific bupropion, (+)-(2S,3S)-2-(3-chlorophenyl)-3,5,5-trimethyl-2-morpholinol for the treatment of anxiety disorder.

Morgan et al. teach that the activity of bupropion resides with its (+) enantiomer metabolite, (+)-(2S,3S)-2-(3-chlorophenyl)-3,5,5-trimethyl-2-morpholinol. Morgan et al.

teach that the (+)-(2S,3S)-2-(3-chlorophenyl)-3,5,5-trimethyl-2-morpholinol is formed from hydroxylation of the tert-butyl group of bupropion. (column 1 , lines 64-67).

It would have been obvious to one of ordinary skill in the art to employ the specific bupropion, (+)-(2S,3S)-2-(3-chlorophenyl)-3,5,5-trimethyl-2-morpholinol for the treatment of anxiety disorder because Jerussi et al. teach that the metabolite of bupropion particularly, (S,S) hydroxybupropion is effective for the treatment of anxiety disorder and because the (+) enantiomer metabolite of bupropion, (+)-(2S,3S)-2-(3-chlorophenyl)-3,5,5-trimethyl-2-morpholinol is a hydroxybupriopion possessing the activity among the metabolites and it is formed form hydroxylation of the bupropion. One would have been motivated to select the most active metabolite bupropion, (+)-(2S,3S)-2-(3-chlorophenyl)-3,5,5-trimethyl-2-morpholinol for the treatment of anxiety disorder in order the achieve an effective therapeutic benefit by administering the most active metabolite obtained by hydroxylation of bupropion. There would have been a reasonable expectation of successfully treating anxiety disorder in human with (+)-(2S,3S)-2-(3-chlorophenyl)-3,5,5-trimethyl-2-morpholinol because the effectiveness of hydroxybupropion metabolites in treatment of anxiety disorders is well known by Jerussi et al. and because (+)-(2S,3S)-2-(3-chlorophenyl)-3,5,5-trimethyl-2-morpholinol is most active hydroxybupropion as reported by Morgan et al.

Claims 6, 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morgan et al. (US 2003/0064988A1) of record.

Morgan et al. teaches the compound, (+)-(2S,3S)-2-(3-chlorophenyl)-3,5,5-trimethyl-2-morpholinol and pharmaceutically acceptable salts and solvates thereof, pharmaceutical compositions comprising them are useful for the treatment of anxiety. (abstract, [0019]. Morgan et al. teaches the composition can be formulated with an optically pure form of the compound or the salts and solvates thereof. ([0002]).

Morgan et al. do not illustrate the administration of the compound for the treatment of anxiety disorder.

It would have been obvious to one of ordinary skill in the art to employ the (+)-(2S,3S)-2-(3-chlorophenyl)-3,5,5-trimethyl-2-morpholinol for the treatment of anxiety disorder because Morgan et al. teach that the compound is useful and effective for the treatment of anxiety condition. One would have been motivated to make such modification in order to achieve an expected benefit of treatment of anxiety disorder, generally taught by Morgan et al.

Claims 6, 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morgan et al. (US 2006/0189612A1).

Morgan et al. teaches the compound, (+)-(2S,3S)-2-(3-chlorophenyl)-3,5,5-trimethyl-2-morpholinol and pharmaceutically acceptable salts and solvates thereof, pharmaceutical compositions comprising them are useful for the treatment of anxiety. (abstract, [0019]. Morgan et al. teaches the composition can be formulated with an optically pure form of the compound or the salts and solvates thereof. ([0002]).

Morgan et al. do not illustrate the administration of the compound for the treatment of anxiety disorder.

It would have been obvious to one of ordinary skill in the art to employ the (+)-(2S,3S)-2-(3-chlorophenyl)-3,5,5-trimethyl-2-morpholinol for the treatment of anxiety disorder because Morgan et al. teach that the compound is useful and effective for the treatment of anxiety condition. One would have been motivated to make such modification in order to achieve an expected benefit of treatment of anxiety disorder, generally taught by Morgan et al.

Claims 6, 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ascher et al. (US 2003/0032643A1).

Ascher et al. teaches the compound, (+)-(2S,3S)-2-(3-chlorophenyl)-3,5,5-trimethyl-2-morpholinol and pharmaceutically acceptable salts and solvates thereof, pharmaceutical compositions comprising them are useful for the treatment of anxiety. (abstract, [0020]. Ascher et al. teaches the composition can be formulated with an optically pure form of the compound or the salts and solvates thereof. ([0002]).

Ascher et al. do not illustrate the administration of the compound for the treatment of anxiety disorder.

It would have been obvious to one of ordinary skill in the art to employ the (+)-(2S,3S)-2-(3-chlorophenyl)-3,5,5-trimethyl-2-morpholinol for the treatment of anxiety disorder because Ascher et al. teach that the compound is useful and effective for the treatment of anxiety condition. One would have been motivated to make such

modification in order to achieve an expected benefit of treatment of anxiety disorder, generally taught by Ascher et al.

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

None of the claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 571-272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jennifer Kim
Primary Examiner
Art Unit 1617

Jmk
October 11, 2007